

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1. (Original): A method for the treatment of a severe form of bone loss diseases in a patient in need of such treatment which comprises administering an effective amount of a c

Claim 2. (Original): The use of a cathepsin K inhibitor in the preparation of a medicament for the treatment of a severe form of bone loss diseases.

Claim 3. (Original): A pharmaceutical composition which incorporates as an active agent a cathepsin K inhibitor for use in the treatment of a severe form of bone loss diseases.

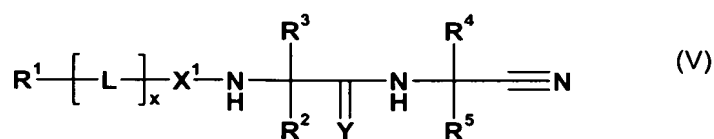
Claim 4. (Currently amended): A method, use or composition according to ~~any preceding~~ claims 1, wherein the cathepsin K inhibitors are used to stimulate bone growth in a patient in need of such a treatment.

Claim ~~6-5~~. (Currently amended): A method, use or composition according to ~~any preceding~~ claims 1, wherein the diseases are a severe form of osteoporosis, osteoarthritis or bone metastasis.

Claim ~~7-6~~. (Currently amended): A method, use or composition according to ~~any preceding~~ claims 1, wherein the disease is severe osteoporosis.

Claim ~~8-7~~. (Currently amended): A method, use or composition according to ~~any preceding~~ claims 1, wherein the disease is severe osteoporosis in postmenopausal women.

Claim ~~9-8~~. (Currently amended): A method, use or composition according to ~~any preceding~~ claims 1, in which the cathepsin K inhibitor is selected from the following compounds of formula V or a pharmaceutically acceptable salt thereof, or any hydrate thereof



wherein

R¹ is optionally substituted (aryl, aryl-lower alkyl, lower alkenyl, lower alkynyl, heterocyclyl or heterocyclyl-lower alkyl);

R² and R³ together represent lower alkylene, optionally interrupted by O, S or NR⁶, so as to form a ring with the carbon atom to which they are attached, and R⁶ is hydrogen, lower alkyl or aryl-lower alkyl;

R⁴ and R⁵ are independently H, or optionally substituted (lower alkyl or aryl-lower alkyl), -C(O)OR⁷, or -C(O)NR⁷R⁸, wherein R⁷ is optionally substituted (lower alkyl, aryl, aryl-lower alkyl, cycloalkyl, bicycloalkyl, bicycloalkyl or heterocyclyl), and R⁸ is H, or optionally substituted (lower alkyl, aryl, aryl-lower alkyl, cycloalkyl, bicycloalkyl, bicycloalkyl or heterocyclyl); or

R⁴ and R⁵ together represent lower alkylene, optionally interrupted by O, S or NR⁶, so as to form a ring with the carbon atom to which they are attached, and R⁶ is hydrogen, lower alkyl or aryl-lower alkyl; or

R⁴ is H or optionally substituted lower alkyl and R⁵ is a substituent of formula -X²-(Y¹)_n-(Ar)_p-Q-Z wherein

Y¹ is O, S, SO, SO₂, N(R⁶)SO₂, N-R⁶, SO₂NR⁶, CONR⁶ or NR⁶CO;

N is zero or one;

P is zero or one;

X² is lower alkylene; or when n is zero, X² is also C₂-C₇-alkylene interrupted by O, S, SO, SO₂, NR⁶, SO₂NR⁶, CONR⁶ or NR⁶CO, and R⁶ is hydrogen, lower alkyl or aryl-lower alkyl;

Ar is arylene;

Z is hydroxyl, acyloxy, carboxyl, esterified carboxyl, amidated carboxyl, aminosulfonyl, (lower alkyl or aryl-lower alkyl)aminosulfonyl, or (lower alkyl or aryl-lower alkyl)sulfonylaminocarbonyl; or Z is tetrazolyl, triazolyl or imidazolyl;

Q is a direct bond, lower alkylene, Y¹-lower alkylene or C₂-C₇-alkylene interrupted by Y¹;

X¹ is -C(O)-, -C(S)-, -S(O)-, -S(O)₂-, or -P(O)(OR⁶)-, and R⁶ is as defined above;

Y is oxygen or sulphur;

L is optionally substituted -Het-, -Het-CH₂- or -CH₂-Het-, and Het is a hetero atom selected from O, N or S; and

X is zero or one; and

aryl in the above definitions represents carbocyclic or heterocyclic aryl.

Claim ~~40~~9. (Currently amended): A method, use or composition according to ~~any preceding~~ claims 1, in which the cathepsin K inhibitor is N-[1-(cyanomethyl-carbamoyl)-cyclohexyl]-4-(4-propyl-piperazin-1-yl)-benzamide, or a pharmaceutically acceptable salt thereof, e.g. the maleate form, or any hydrate thereof.

Claim ~~41~~10. (Currently amended): A pharmaceutical composition comprising less than 50.1 mg N-[1-(cyanomethyl-carbamoyl)-cyclohexyl]-4-(4-propyl-piperazin-1-yl)-benzamide or a pharmaceutically acceptable salt thereof wherein the amount of the base form is less than 50.1 mg.

Claim ~~42~~11. (Currently amended): The pharmaceutical composition according to claim 11 comprising less than 64.2 mg N-[1-(cyanomethyl-carbamoyl)-cyclohexyl]-4-(4-propyl-piperazin-1-yl)-benzamide maleate.

Claim ~~43~~12. (Currently amended): All novel compounds, processes, pharmaceutical compositions, methods and uses substantially as hereinbefore described with particular reference to the Examples.